UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

FEDERAL TRADE COMMISSION,	:	CIVIL ACTION
Plaintiff,	:	
v.	:	Case No. 14-cv-5151
ABBVIE, INC., et al.,	:	
Defendants.	:	

[PROPOSED] ORDER

The matter is before the Court on the Motion for Summary Judgment on Count I of the Complaint, filed by Defendants Abbvie Inc., Abbott Laboratories, Unimed Pharmaceuticals LLC, and Besins Healthcare, Inc. Upon consideration of the contentions and arguments of the Parties, the Court hereby **ORDERS**:

Defendants' Motion for Summary Judgment on Count I of the Complaint is **GRANTED**.

Count I of the Complaint is **DISMISSED** with prejudice.

Judgment is entered in favor of Defendants Abbvie Inc., Abbott Laboratories, Unimed Pharmaceuticals LLC, and Besins Healthcare, Inc. on Count I of the Complaint.

Dated: _____

_____
The Honorable Harvey Bartle, III
United States District Judge

UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

FEDERAL TRADE COMMISSION,	:	CIVIL ACTION
Plaintiff,	:	
v.	:	Case No. 14-cv-5151
ABBVIE, INC., et al.,	:	ORAL ARGUMENT REQUESTED
Defendants.	:	

ABBVIE AND BESINS DEFENDANTS' MOTION FOR SUMMARY JUDGMENT ON COUNT I OF THE COMPLAINT

(Public Version – Confidential Information Redacted)

Defendants AbbVie, Inc., Abbott Laboratories, Unimed Pharmaceuticals, LLC, and Besins Healthcare, Inc. hereby move this Court pursuant to Rule 56 of the Federal Rules of Civil Procedure for an order granting summary judgment to the AbbVie and Besins Defendants[1] on Count I of the Complaint. Pursuant to Local Rule 7.1, this Motion is based on the Memorandum in Support of AbbVie and Besins Defendants' Motion for Summary Judgment on Count I of the Complaint, the accompanying exhibits, and the accompanying declarations, filed on February 5, 2015. The AbbVie and Besins Defendants request that the Court hear oral argument on the Motion at a date and time to be determined by the Court.

[1] AbbVie refers to AbbVie, Inc., Abbott Laboratories, and Unimed Pharmaceuticals, LLC; Besins refers to Besins Healthcare, Inc.

Dated: February 6, 2015

Respectfully submitted,

/s/ *Paul H. Saint-Antoine*

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UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

FEDERAL TRADE COMMISSION, Plaintiff, v. ABBVIE INC. et al., Defendants.	CIVIL ACTION Case No. 14-cv-5151 ORAL ARGUMENT REQUESTED

MEMORANDUM IN SUPPORT OF ABBVIE AND BESINS DEFENDANTS' MOTION FOR SUMMARY JUDGMENT ON COUNT I OF THE COMPLAINT

(FILED UNDER SEAL)

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I. INTRODUCTION

Count I of the Complaint alleges illegal monopolization based on the filing of alleged sham litigations by Defendants AbbVie Inc., Abbott Laboratories, Unimed Pharmaceuticals LLC, and Besins Healthcare, Inc. ("Defendants").[1] In the underlying patent cases at issue, referred to herein as the "Perrigo Litigation" and the "Teva Litigation," these Defendants asserted a patent covering the brand-name drug AndroGel against two manufacturers that sought approval for generic versions of that very drug. Under the *Noerr-Pennington* doctrine, an "effort to influence the exercise of government power, even for the purpose of gaining an anticompetitive advantage, does not create liability under the antitrust laws." *FilmTec Corp. v. Hydranautics*, 67 F.3d 931, 937 (Fed. Cir. 1995). In particular, the doctrine "generally immunizes a party from antitrust liability based on its filing of a lawsuit." *ERBE Elektromedizin GmbH v. Canady Tech. LLC*, 629 F.3d 1278, 1291 (Fed. Cir. 2010). The only relevant potential exception is the narrow one for "sham litigation," an essential element of which is the plaintiff's proving the underlying litigations were "objectively baseless." *See Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 60 (1993) ("*PRE*"). "Objective baselessness" is an exacting standard, provable in only the "rare" circumstance, *id.* at 75, (Stevens, J., concurring in the judgment), in which the facts and law show that "no reasonable litigant could realistically expect success on the merits." *Id.* at 60-61 (majority opinion). Defendants move for summary judgment on Count I because the undisputed facts show that the FTC cannot prove that the underlying litigations here were objectively baseless.

While this FTC antitrust litigation is at an early stage, summary judgment is appropriate because "there is no dispute over the predicate facts of the underlying legal proceeding." *Id.* at 63. If there is no issue of objective baselessness, the courts do not reach the second prong of the

[1] For simplicity, this motion refers to "Defendants" where the distinctions among the moving parties are not relevant to the motion, even though not all moving parties participated in all of the referenced events and those distinctions may be relevant in other contexts. Count I is not against Defendant Teva Pharmaceuticals USA, Inc.

sham litigation inquiry—subjective motivation. "Only if challenged litigation is objectively meritless may a court examine the litigant's subjective motivation." *Id.* at 60.[2]

A plaintiff asserting sham litigation must affirmatively prove that there was *no* competent evidence or *no* law supporting the claims asserted in the underlying litigation. The mere existence of some evidence (even if controvertible) and some legal authority (even if conflicting with other legal authority) therefore defeats a sham litigation claim as a matter of law—as explained by another district court that previously granted summary judgment dismissing allegations of sham litigation regarding this same patent by these same Defendants. *See In re AndroGel Antitrust Litig. (No. II)*, 888 F. Supp. 2d 1336, 1344-45 (N.D. Ga. 2012). Because such evidence and legal authority both exist here, the Court can and should grant summary judgment in Defendants' favor on Count I at this time.[3]

The Perrigo Litigation. As a threshold matter, the objective reasonableness of the Perrigo litigation is established by the undisputed fact that the parties to that litigation settled with a compromise to split the patent term and without any alleged "reverse payment." For more than a decade, the FTC has represented to numerous courts that settlements of this kind are the *best* evidence of the strength of the patent holder's case. Where, as here, there was a meaningful compromise by the accused infringer on the entry date for its product, it necessarily follows that the patent litigation was not objectively baseless.

The direct evidence also refutes the Complaint's allegation that the Perrigo litigation was objectively baseless. The litigation was based on Defendants' contention that Perrigo's generic AndroGel product infringed Unimed's '894 patent that covered a topical testosterone gel using a

[2] Defendants reserve the right to raise arguments in support of objective reasonableness additional to those stated herein, at other stages of this litigation.

[3] Before filing this suit, the FTC conducted a formal, multi-year investigation that included numerous document subpoenas, interrogatories and "investigational hearings" in which officers of the FTC took witness testimony under oath. While the FTC may view the merits of Defendants' underlying infringement claims against Teva and Perrigo differently from Defendants, the facts and law establishing that these claims were not objectively baseless at the time filed can be fully evaluated now, without further discovery.

particular penetration enhancer in a particular concentration. While the Perrigo product did not use the same penetration enhancer, Defendants relied on the doctrine of equivalents, under which a product that does not literally infringe a particular element of a patent claim will nevertheless be found to infringe if it is a "substantial equivalent" to that element. It cannot seriously be disputed that there was a reasonable argument based on the science that the penetration enhancer of Perrigo's formulation was an equivalent to the one specified in the patent claim under the patent law. Indeed, in its detailed paragraph IV certification letter setting forth the bases for its assertion of noninfringement, Perrigo itself did not deny that its penetration enhancer was an equivalent.

The Complaint essentially ignores this direct evidence regarding equivalence and instead plucks supposedly inconsistent language from arguments to the FDA and the Patent Office about distinctions between the penetration enhancers. *See, e.g.*, Compl. ¶¶ 7, 76. But these statements, and others like them, addressed different questions with different standards from the question of and standard for determining equivalence under the patent laws. The Complaint does not challenge the factual foundation for Defendants' claim that Perrigo's penetration enhancer met the legal test for "equivalence" to the penetration enhancer claimed in the patent for purposes of an infringement analysis.

Moreover, even if these statements were relevant, the ultimate determinations by FDA and the Patent Office support the reasonableness of Defendants' litigation position. The FDA ultimately concluded that Perrigo's product *was* bioequivalent, and the Patent Office concluded that Perrigo's penetration enhancer *was* interchangeable with the one literally claimed in Unimed's patent and on that basis rejected Unimed's later-filed claims. Finally, with this motion, Defendants are submitting an expert declaration from Dr. Pankaj Karande, Associate Professor of Chemical and Biological Engineering at Rensselaer Polytechnic Institute, who opines that the two penetrations enhancers meet the patent standard for equivalence. Taken together, this evidence conclusively shows that Defendants had an objectively reasonable basis for alleging infringement under the doctrine of equivalents.

The Complaint also invokes the doctrine of prosecution history estoppel ("PHE"). Under this doctrine, a patentee may, under certain circumstances, be estopped from claiming that something is equivalent to a claim element where it was specifically contained in an earlier version of the proposed claim but dropped in an amendment. The Complaint alleges that Perrigo's penetration enhancer was mentioned in the claims in the original patent application but dropped in an amendment. Compl. ¶ 93. But that means only that the circumstances relevant to the amendment would need to be examined in the underlying patent litigation to determine whether PHE applies; it does not dictate that PHE would have applied. Further, PHE itself must be "applied . . . in a flexible way, not a rigid one." *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 738 (2002).

One aspect of the flexibility in application of PHE is that the doctrine does not apply unless the element in question was dropped from the literal scope of the patent claim for "purposes of patentability." *Id.* at 739-40. As shown below, Defendants had a reasonable argument that the Perrigo penetration enhancer was not dropped from the patent claim for "purposes of patentability." The amendment here arguably was not made in response to a Patent Office rejection of the claims as previously formulated. The Supreme Court in *Festo* emphasized the importance to the PHE inquiry of a Patent Office rejection, and no case subsequent to that decision has found that an amendment was made for purposes of patentability where the amendment was not made in response to a rejection.

The Teva Litigation. The undisputed facts similarly refute the FTC's contention that Defendants' assertion of patent infringement against Teva was objectively baseless. The FTC does not appear to challenge the reasonableness of Defendants' contention that Teva's penetration enhancer (isopropyl palmitate) met the legal test for equivalence to the penetration enhancer claimed in the patent (isopropyl myristate). The FTC's principal contention appears to be, instead, that there was no reasonable argument against application of PHE.

But the FTC is simply wrong. An additional limitation on PHE is that it does not apply if the amendment is "tangential" to the claimed equivalent. *Festo*, 535 U.S. at 740-41 (no

prosecution history estoppel if "the rationale underlying the amendment . . . bear[s] no more than a tangential relationship to the equivalent"). Applying *Festo*, the Federal Circuit and a number of district courts have refused to apply PHE in this circumstance. *Insituform Techs., Inc. v. CAT Contracting, Inc.*, 385 F.3d 1360, 1369-70 (Fed. Cir. 2004); *accord Primos, Inc. v. Hunter's Specialities, Inc.*, 451 F.3d 841, 848-49 (Fed. Cir. 2006); *McKesson Automation, Inc. v. Swisslog Italia S.P.A.*, 712 F. Supp. 2d 283, 302-03 (D. Del. 2010); *Engineered Prods. Co. v. Donaldson Co.*, 313 F. Supp. 2d 951, 973-74 (N.D. Iowa 2004).

Here, the Complaint merely alleges the conclusion that any relevant amendments "were not tangential." Compl. ¶ 95. Defendants disagree, but the issue here is not what the outcome would have been in the underlying patent case, but whether there was a reasonable argument that the relevant amendment was tangential. The undisputed facts show that there was. Expert testimony is relevant to determine tangentiality. *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 457 F.3d 1293, 1312-13 (Fed. Cir. 2006). Teva filed a summary judgment motion in the patent litigation, claiming that PHE barred the application of the doctrine of equivalents. In declining to rule on Teva's motion, the district court ordered discovery, and stated that if the parties submitted conflicting expert opinions on the tangentiality exception, the motion would probably be denied and the case would proceed to trial.[4] With this motion, Defendants are submitting an expert declaration by Dr. Jonathan Hadgraft, a renowned expert on topical and transdermal gels and a consultant disclosed to Teva in the patent litigation. Dr. Hadgraft opines that the amendment in question was at most tangentially related to Teva's penetration enhancer. Dr. Hadgraft provides specific and detailed scientific support for that opinion, and is eminently qualified to offer it. By itself, this declaration shows that there was reasonable basis for finding that PHE did not apply, and that Defendants had a reasonable basis for arguing that Teva's

[4] Ex. 24, Dkt. 65, Hr'g Tr., Oct. 14, 2011, at 75, *Abbott Prods., Inc. v. Teva Pharms. USA, Inc.*, No. 1:11-cv-384 (D. Del.) ("[T]he *Festo* case seems to allow expert -- some expert testimony. If there are experts, it's likely that they're not going to agree. If they don't agree, summary judgment probably would be denied.").

penetration enhancer was an equivalent to the one specified in the patent. *Honeywell Int'l, Inc. v. Universal Avionics Sys. Corp.*, 343 F. Supp. 2d 272, 325-26 (D. Del. 2004), *aff'd in relevant part*, 488 F.3d 982 (no sham litigation because patentee had highly qualified expert backing infringement theory). Where there is a genuine issue for trial, there is clearly a reasonable basis for the litigation. *PRE*, 508 U.S. at 61 ("To be sham, therefore, litigation must fail to be 'genuine' . . . ."); *Shire LLC v. Sandoz, Inc.*, 2008 WL 4402251, at *13 (D. Colo. Sept. 24, 2008) (no sham litigation where court found the "existence of issues of material fact regarding the infringement").

To be sure, Perrigo and Teva each disputed liability in their respective underlying patent cases, as accused infringers often do. The mere existence of those disputes, however, is insufficient as a matter of law to show that Defendants' lawsuits were sham. *PRE*, 508 U.S. at 65 (plaintiff "could not pierce [defendant's] *Noerr* immunity without proof that [defendant's] infringement action was objectively baseless or frivolous"). The Court should grant summary judgment to Defendants on Count I.

II. BACKGROUND

A. AndroGel

AndroGel is a daily-use transdermal 1% testosterone gel treatment for hypogonadism. Developed through a collaboration between Besins and Unimed, AndroGel produces consistent testosterone blood levels in the patient, an improvement over pre-existing treatments (such as injections) that were less convenient and produced peaks and valleys in testosterone levels. Unimed filed its New Drug Application ("NDA"), No. 21-015, for AndroGel on April 28, 1999. The FDA approved that application on February 28, 2000. Unimed received a three-year regulatory exclusivity period under 21 U.S.C. § 355(j)(5)(F)(iii), expiring on February 28, 2003.

On August 30, 2000, Unimed and Besins jointly filed patent application no. 09/651,777 (the "'777 application") for AndroGel. (For simplicity, we refer to the patent applicants Unimed and Besins as "Unimed.") On January 7, 2003, the U.S. Patent and Trademark Office ("PTO") issued the '777 application as U.S. Patent No. 6,503,894 (the "'894 patent"). The '894 patent

expires on August 30, 2020. AndroGel also was eligible for, and several years later received, an additional six months of regulatory exclusivity for pediatric studies under 21 U.S.C. § 355a(b)(1)(B).

B. The '894 Patent Prosecution History

1. *Facts Relevant to the "First Amendment" and Applicability of PHE to Teva's Product*

When originally filed, the '777 application included the following claims:

> 1. A pharmaceutical composition useful for the percutaneous delivery of an active pharmaceutical ingredient, comprising: (a) a C1-C4 alcohol; (b) a penetration enhancer; (c) the active pharmaceutical ingredient; and (d) water.
>
> . . . .
>
> 5. A composition of claim 1 wherein the active pharmaceutical ingredient is testosterone, and the enhancer is isopropyl myristate.[5]

In an Office Action dated June 19, 2001, the patent examiner rejected these initial claims as obvious (under then-35 U.S.C. § 103(a)) over certain prior art, principally *Mak*, that disclosed a transdermal testosterone formulation using *oleic acid* as the penetration enhancer.[6] The examiner acknowledged that "[t]he prior art does not expressly disclose the employment of the particular penetration enhancer, isopropyl myristate," that is used in AndroGel.[7] The examiner initially found, however, that it would have been obvious to employ isopropyl myristate in a testosterone gel when *Mak* was considered in view of other prior art, *Allen*, because *Allen* disclosed isopropyl myristate to be "useful for facilitating the transdermal delivery of pharmaceuticals"—in the context of an active ingredient that was not testosterone.[8]

Following this Office Action, Unimed amended the claims on October 19, 2001.[9] Rather than generically claiming "a penetration enhancer," Unimed enumerated a large number of

[5] Ex. 1, '777 application at UCFH 0080.
[6] Ex. 2, Office Action at UCFH 1900 (June 19, 2001).
[7] *Id.* at UCFH 1901.
[8] *Id.*
[9] Ex. 3, Amendment and Response to June 19, 2001 Office Action (Oct. 19, 2001).

particular penetration enhancers. The amendment omitted oleic acid—which was discussed in *Mak*. The amendment also omitted isopropyl palmitate and is therefore the relevant amendment —referred to below as the "First Amendment"—to the potential applicability of PHE to Teva's product (whose penetration enhancer is isopropyl palmitate). As amended, claim 1 read:

> A pharmaceutical composition useful for the percutaneous delivery of an active pharmaceutical ingredient, consisting essentially of (a), at least one penetration enhancer selected from the group consisting of isostearic acid, octanoic acid, lauryl alcohol, ethyl oleate, isopropyl myristate, butyl stearate, methyl laurate, disopropyl adipate, glyceryl monolaurate, tetrahydrofurfuryl alcohol, polyethylene glycol ether, polyethylene glycol, propylene glycol, 2-(2-ethoxyethoxy) ethanol, diethylene glycol monomethyl ether, alkylaryl ethers of polyethylene oxide, polyethylene oxide monomethyl ethers, polyethylene oxide dimethyl ethers, dimethyl sulfoxide, glycerol, ethyl acetate, acetoacetic ester, N-alkylpyrrolidone, terpene, and combinations of any of the foregoing; and (b) testosterone.[10]

Unimed also added new claims to the '777 application, including claims 47 and 61—which identified the penetration enhancer as isopropyl myristate, or one of either isopropyl myristate and lauryl alcohol.[11]

In connection with the First Amendment, Unimed argued to the PTO that none of the cited prior art references disclosed a testosterone composition made with the penetration enhancers enumerated in amended claim 1. In addition, Unimed argued that the examiner was unfounded in her prior conclusion that all penetration enhancers are equivalent and freely interchangeable regardless of the active ingredient in a particular drug.[12] Unimed *did not* make any arguments that were based on the dropping of isopropyl palmitate from the literal scope of the claims.[13] In fact, as shown below, the just-discussed arguments in favor of patentability all would have applied equally if isopropyl palmitate had not been dropped. As will be discussed further below, this is relevant to the issue of PHE because it is relevant to whether the rationale underlying the First Amendment "bear[s] no more than a tangential relationship to the equivalent."

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[10] *Id.* at UCFH 1962.
[11] *Id.* at UCFH 1964 to UCFH 1966.
[12] *Id.* at UCFH 1976 to UCFH 1981.
[13] *Id.*

2. *Facts Relevant to the "Second Amendment" and Applicability of PHE to Perrigo's Product*

In an interview on December 6, 2001, the examiner stated that claim 61 would be allowable over the prior art she had cited.[14] The examiner did not make any statement, positive or negative, about the patentability of a composition of testosterone with any other penetration enhancer. The examiner also stated that her prior art search for claim 47 would "be updated" in light of Unimed's argument that the prior art failed to disclose the penetration enhancers in "the composition [testosterone] with particular concentration."[15]

Unimed amended the claims again on December 21, 2001, with a supplementation on February 8, 2002.[16] This is referred to collectively below as the "Second Amendment," and is the amendment relevant to the application of PHE to Perrigo's product because it was the amendment in which Perrigo's penetration enhancer, isostearic acid, was first omitted.

Significantly to the PHE issue of whether the Second Amendment was made for purposes of patentability (as will be discussed below), there was no further rejection or other office action by the examiner prior to Unimed's submission of the Second Amendment. The Second Amendment canceled a number of claims, including claim 1. As noted, claim 1 was that claim that had previously included isostearic acid within its literal scope. Unimed also amended claims 47 and 61, which the examiner had indicated she would either consider based on an updated prior art search (claim 47) or allow (claim 61). As amended, claim 47 now specified "isopropyl myristate" alone as the penetration enhancer, instead of "a penetration enhancer selected from the group consisting of isopropyl myristate and lauryl alcohol."[17] As amended, claim 61 now specified "about 0.1% to about 5% isopropyl myristate" instead of "about 0.1% to about 2% isopropyl myristate."[18] As noted above, the examiner had *not* stated in the December 2001

[14] Ex. 4, Interview Summary (Dec. 6, 2001).
[15] *Id.*
[16] Ex. 5, Supp'l Amendment (Dec. 21, 2001); Ex. 6, Supp'l Amendment II (Feb. 8, 2002).
[17] Ex. 5, Supp'l Amendment at UCFH 2049 (Dec. 21, 2001).
[18] *Id.* at UCFH 2042.

interview that she was inclined to reject any claim, and *had* suggested that she was inclined to allow certain claims that were limited to isopropyl myristate as the penetration enhancer. Unimed's Second Amendment thus simplified the application to accord with the subject matter that the examiner said she was inclined to allow.

3. *Issuance of the '894 Patent*

The '894 patent issued on January 7, 2003. As reflected in the examiner's Notice of Allowability, the patent included amended claims 47 and 61 (with some further slight amendments), as well as various dependent claims and other claims.[19] Unimed used separate patent applications to continue to pursue amended claim 1 and various other claims that were cancelled from the '894 application in the December 2001 and February 2002 amendments.[20]

C. Perrigo's NDA for Generic AndroGel and the Ensuing Patent Litigation

On July 5, 2011, Perrigo filed NDA No. 203-098 to market its generic version of AndroGel, in which Perrigo attempted to design around the '894 patent by using a penetration enhancer known as isostearic acid. Compl. ¶ 3. On September 20, 2011, Perrigo notified Defendants that its NDA contained a paragraph IV certification under 21 U.S.C. § 355(b)(2)(A)(iv), alleging that the '894 patent was invalid, unenforceable and/or not infringed. With respect to infringement, Perrigo's paragraph IV notice asserted that its proposed generic

[19] Ex. 7, Notice of Allowability at UCFH 2300 (Aug. 8, 2002). The '894 patent contains different claim numbering because when an application is ready for issuance, the PTO renumbers the allowed claims consecutively starting from 1. *See* 37 C.F.R. § 1.126.

[20] Specifically, at the time of amendment on December 21, 2001, Unimed had two other pending patent applications that claimed priority to the '894 patent and covered the list of the broad group of penetration enhancers that were removed in the December 2001 amendment. *See* Ex. 9, U.S. Patent App. No. 10/033,101, claim 22 (Oct. 19, 2001); Ex. 10, U.S. Patent App. No. 10/046,454, claim 22 (Oct. 19, 2001). Moreover, since December 21, 2001, the PTO has published several patent applications claiming priority to the '894 patent. These applications, which were based on essentially the same disclosure relating to the penetration enhancer as the '894 patent, each includes claims to a "penetration enhancer" not limited to isopropyl myristate. *See, e.g.*, Ex. 11. U.S. Patent App. No. 10/867,445, claim 1 (June 14, 2004) ("A hydroalcoholic gel pharmaceutical composition, comprising: (a) about 0.1 % to about 10% testosterone weight to weight of the composition; (b) an alcohol; (c) a penetration enhancer; and (d) a gelling agent; wherein upon administration of the pharmaceutical composition to skin of a male subject, the testosterone is absorbed into bloodstream . . . .").

product did not contain "about 0.1% to about 5% isopropyl myristate" as claimed in the '894 patent, and that doctrines including prosecution history estoppel precluded infringement under the doctrine of equivalents because Unimed "amended the pending claims in response to a rejection" during prosecution.[21]

On October 31, 2011, Defendants filed suit against Perrigo for patent infringement.[22] Defendants contended that Perrigo's proposed product infringed under the doctrine of equivalents. Under that doctrine, an element of a product that is not literally covered by a patent claim can still be found to be covered if it performs substantially the same function in substantially the same way to achieve substantially the same result as an element in the patent claim. *See, e.g.*, *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 35-36 (1997). Although Perrigo's penetration enhancer, isostearic acid, was not isopropyl myristate (the penetration enhancer in AndroGel, claimed in the '894 patent), Perrigo did not dispute in its paragraph IV notice letter that its penetration enhancer performed substantially the same function in substantially the same way to achieve substantially the same result as the claimed penetration enhancer.[23]

On December 8, 2011, prior to any motion practice or other order of the court in the patent litigation, the parties resolved the litigation with a settlement and license agreement, which permitted Perrigo to enter with its generic product beginning no later than January 1, 2015—some 5.5 years before the expiration of the '894 patent.[24] Relevant to that agreement was a consent decree previously entered into between Perrigo and the FTC in conjunction with Perrigo's acquisition of assets from another generic company, Paddock Laboratories. In the

[21] Ex. 13, Perrigo Notification of Certification at 1, 21-22, 24-26, 28-29, 32, 37 (Sept. 20, 2011).
[22] Ex. 14, Dkt. 1, Compl., *Abbott Prods., Inc. v. Perrigo Co.*, No. 3:11-cv-6357 (D.N.J.).
[23] Ex. 13, Perrigo Notification of Certification (Sept. 20, 2011).
[24] Ex. 15, Binding Term Sheet, dated December 8, 2011, between Abbott Products, Inc., Unimed Pharmaceuticals, LLC, Besins Healthcare Inc., Perrigo Israel Pharmaceuticals, Ltd., and Perrigo Company.

consent decree, Perrigo agreed that it would not settle patent litigation regarding generic AndroGel in which the consideration that it received went beyond the following:

> (1) the right to market the Relevant Testosterone Gel Product in the United States prior to the expiration of (a) any patent that is the basis for the patent infringement claim, or (b) any patent right or other statutory exclusivity that would prevent the marketing of the Relevant Testosterone Gel Product; and/or
>
> (2) a payment for reasonable litigation expenses not to exceed $2,000,000;
>
> (3) a covenant not to sue on any claim that the Relevant Testosterone Gel Product infringes a United States patent.[25]

Consistent with the consent decree, Perrigo agreed to a license of all AndroGel patents beginning no later than January 1, 2015, and not to market its generic AndroGel prior to the license date. [redacted] The FTC has not challenged that settlement under the Perrigo consent decree or any aspect of the antitrust laws.

D. Teva's NDA for Generic AndroGel and the Ensuing Patent Litigation

On January 14, 2011, Teva filed NDA No. 202-763 for approval of its generic version of AndroGel. Teva, like Perrigo, attempted to design around the '894 patent by using a different penetration enhancer (isopropyl palmitate). Compl. ¶ 3. On March 16, 2011, Teva notified Defendants that its NDA contained a paragraph IV certification under 21 U.S.C. § 355(b)(2)(A)(iv), alleging that the '894 patent was invalid, unenforceable and/or not infringed. Teva's principal argument appeared to be noninfringement—and, in particular, that the '894 patent covered only testosterone in combination with isopropyl myristate.[26]

On April 29, 2011, Defendants filed a complaint alleging that Teva's product infringed the '894 patent[27] under the doctrine of equivalents.[28] Notably, although Teva's penetration

[25] Ex. 16, Decision and Order at 21-22, *In the Matter of Perrigo Co.*, FTC Docket No. C-4329 (FTC File No. 111-0083) (July 26, 2011).
[26] Ex. 17, Teva Notice of Certification at 14-15 (Mar. 16, 2011).
[27] Ex. 18, Dkt. 1, Compl., *Abbott Prods., Inc. v. Teva Pharms. USA, Inc.*, No. 1:11-cv-384 (D. Del.).
[28] Ex. 19, Abbott's Responses to Teva's Amended First Set of Interrogatories at 4-12.

enhancer, isopropyl palmitate, was not isopropyl myristate (the penetration enhancer in AndroGel, claimed in the '894 patent), the FTC Complaint does not allege that it was unreasonable for Defendants to contend that Teva's penetration enhancer performs substantially the same function in substantially the same way to achieve substantially the same result as the claimed penetration enhancer. Indeed, Teva acknowledged in its NDA that isopropyl palmitate "was selected as a penetration enhancer as it is chemically similar to isopropyl myristate."[29] Moreover, in its paragraph IV notice letter detailing the bases for its claim of noninfringement, Teva did not allege that isopropyl palmitate and isopropyl myristate were not equivalent as penetration enhancers in a testosterone gel formulation.

About three months after Defendants filed the complaint, Teva filed an early motion for summary judgment of noninfringement. Teva principally asserted that Defendants' assertion of the doctrine of equivalents was precluded by PHE.[30] Defendants responded to Teva's motion by cross-moving under Fed. R. Civ. P. 56(d), asking the district court to require discovery on issues relevant to the doctrine of equivalents and PHE.[31] As Defendants noted, PHE may preclude a finding of infringement under the doctrine of equivalents where the patent application originally claimed the equivalent but the applicant surrendered that equivalent by amendment for purposes of patentability. Defendants explained, however, that the Supreme Court in *Festo* expressly reversed the Federal Circuit's attempt to impose a bright line rule that PHE always applied in this circumstance. The Supreme Court rejected such a "*per se*" rule as inconsistent with the underlying purposes of the doctrine.[32] The Court held, instead, that the patentee can avoid PHE even where a narrowing claim amendment was made in response to a rejection for purposes of patentability, by showing either that the equivalent was unforeseeable at the time of the patent

[29] Ex. 20 at 21.
[30] Ex. 21, Dkt. 29, Opening Brief in Support of Teva's Motion for Summary Judgment of No Infringement at 16-24, *Abbott Prods., Inc. v. Teva Pharms. USA, Inc.*, No. 1:11-cv-384 (D. Del.).
[31] Ex. 22, Dkt. 47, Opening Brief in Support of Plaintiffs' Motion Pursuant to Fed. R. Civ. P. 56(d), *Abbott Prods., Inc. v. Teva Pharms. USA, Inc.*, No. 1:11-cv-384 (D. Del.).
[32] *Id.* at 8-9 (citing *Festo*, 535 U.S. at 738-39).

application, that *the rationale for the amendment dropping the equivalent bears no more than a tangential relationship to the equivalent*, or that the amendment was made for "some other reason" unrelated to patentability.[33] The Federal Circuit has recognized that these issues may turn on underlying facts, such as how those skilled in the art would interpret the prosecution history.[34]

The claim amendment relevant to Teva's PHE argument was the October 2001 First Amendment because, with the First Amendment, the amended claims for the first time no longer literally covered Teva's penetration enhancer, isopropyl palmitate. In response, Defendants contended that the purpose of the First Amendment was to overcome the prior art cited by the examiner, which disclosed *oleic acid* as a penetration enhancer.[35] Defendants further argued that isopropyl palmitate (the penetration enhancer in Teva's product) is virtually identical to isopropyl myristate (the penetration enhancer claimed in the '894 patent), that both chemicals are very different from oleic acid—which has a different mechanism of action resulting from different physical characteristics—and that these differences were the reasons why the *Mak* prior art reference that disclosed oleic acid did not render the use of isopropyl myristate obvious. This argument distinguishing oleic acid from isopropyl myristate *applied equally to distinguishing oleic acid from isopropyl palmitate*. Accordingly, the deletion of isopropyl palmitate from claim 1, as part of the deletion of oleic acid, bore at best a peripheral or tangential relationship to the reason that the amendment was submitted—namely, to overcome the prior art disclosing oleic acid.[36]

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[33] *Id.* at 9 (citing *Festo*, 535 U.S. at 740-41).

[34] *Id.* at 1, 9-10, 14 (citing *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 344 F.3d 1359, 1365 (2003)).

[35] *Id.* at 1-2; Ex. 23, Dkt. 48, Declaration of Ted G. Dane in Support of Plaintiffs' Rule 56(d) Motion ¶¶ 4-7, *Abbott Prods., Inc. v. Teva Pharms. USA, Inc.*, No. 1:11-cv-384 (D. Del.).

[36] Ex. 22, Dkt. 47, Opening Brief in Support of Plaintiffs' Motion Pursuant to Fed. R. Civ. P. 56(d) at 16, *Abbott Prods., Inc. v. Teva Pharms. USA, Inc.*, No. 1:11-cv-384 (D. Del.) ("Plaintiffs intend to show . . . that a rationale for [the October 2001] amendment—narrowing to exclude the oleic acid/testosterone formulations disclosed in the prior art—is tangential to the claimed equivalent here, isopropyl palmitate, a compound having little resemblance to oleic acid, and much closer resemblance to isopropyl myristate, the enhancer that the Examiner allowed to be

In their Rule 56(d) cross-motion, Defendants set forth specific subject matters for which expert discovery on the issue of tangentiality would be relevant. For example, Defendants argued that the district court would need to understand "the differences or similarities between oleic acid, which prompted [Unimed's October 2001] amendment, on the one hand, and isopropyl myristate, which the examiner found to be patentable, on the other" and then "consider how isopropyl palmitate compares to oleic acid, the prior art penetration enhancer that Unimed omitted from the amended claims, on the one hand, and isopropyl myristate, which the examiner ultimately clearly concluded was a patentable penetration enhancer, on the other."[37]

The district court agreed with Defendants and, in lieu of ruling on Teva's motion for summary judgment, permitted the parties to take certain discovery, including expert discovery. The district court also said that, if Defendants introduced expert testimony supporting their position, then the court would "probably" deny summary judgment—meaning, of course, that the court would find that there was a genuine issue for trial and sufficient admissible evidence to support (but not necessitate) a ruling in Defendants' favor. Specifically, at a hearing on October 14, 2011, the district court stated:

> The *Festo* case seems to allow expert -- some expert testimony. If there are experts, it's likely that they're not going to agree. If they don't agree, summary judgment probably would be denied.[38]

The district court's remarks accorded with Federal Circuit precedents that relied on expert testimony in determining tangentiality.[39]

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included in the issued claims. Plaintiffs would intend to show that isopropyl palmitate shares the very properties that distinguished isopropyl myristate from oleic acid, and that led the Examiner to allow the patent to issue.") (footnote omitted).

[37] *Id.* at 15.

[38] Ex. 24, Dkt. 65, Hr'g Tr., Oct. 14, 2011, at 75, *Abbott Prods., Inc. v. Teva Pharms. USA, Inc.*, No. 1:11-cv-384 (D. Del.).

[39] *See, e.g.*, *Amgen*, 457 F.3d at 1313 (noting that, for purposes of determining tangentiality, it may be "necessary" for the court to consider "expert testimony to aid in interpretation of th[e prosecution] record"); *see also Insituform*, 385 F.3d at 1368 (deciding tangentiality "because the record has been *fully* developed on this point" (emphasis added)).

During the *Teva* litigation, Defendants disclosed consultants who were to be given access to Teva's NDA. One of those was Professor Jonathan Hadgraft, an Emeritus Professor of Biophysical Chemistry at University College London. The case settled before expert reports were exchanged, but with this motion Defendants have included a declaration of Professor Hadgraft that addresses the issues that Defendants identified for expert testimony in its response to Teva's summary judgment motion, and which concludes as follows:

> 8. I have also been asked to consider whether the person of ordinary skill in the art of topical and transdermal drug delivery reviewing the prosecution history of the '894 patent would have viewed the patent applicant's reason for amending claim 1 of the patent application to be tangential to Teva's penetration enhancer, isopropyl palmitate. **As detailed more fully below, it is my opinion that the patent applicant amended claim 1 to avoid prior art disclosing another penetration enhancer, oleic acid, and that the rationale for this amendment at most only tangentially related, if at all, to isopropyl palmitate.**
>
> 9. In forming this opinion, I have considered the properties of isopropyl myristate and isopropyl palmitate, on the one hand, and oleic acid, on the other. As discussed and described more fully below, isopropyl palmitate and isopropyl myristate are very similar chemically related substances that employ the same mechanism of action in the skin. One skilled in the art of transdermal formulations at the time the patent application was filed (as now) would have viewed isopropyl palmitate as interchangeable with isopropyl myristate as a penetration enhancer in a transdermal testosterone gel. Oleic acid, in contrast, has a fundamentally different chemical structure from isopropyl myristate and isopropyl palmitate and employs a different mechanism of action in the skin.
>
> 10. **Accordingly, the reasons given by the patent applicant for amending claim 1 to cover isopropyl myristate apply equally to isopropyl palmitate.** Specifically, isopropyl myristate and isopropyl palmitate both lack a double bond in their carbon chains and have shorter alkyl chains than oleic acid. In addition, oleic acid has a different functionality that isopropyl myristate and isopropyl palmitate lack because oleic acid has a terminal carboxyl group rather than an ester headgroup. Isopropyl palmitate, like isopropyl myristate and unlike oleic acid, thus enhances permeation without disrupting the structured lipid bilayers of the SC. **Accordingly, it is my opinion that isopropyl palmitate bears at most only a peripheral or tangential relation to the reason the claim amendment was submitted, which was to overcome prior art disclosing a testosterone gel made with oleic acid.**

Hadgraft Decl. ¶¶ 8-10 (emphases added). In short, Professor Hadgraft's expert opinion is that the science supported Defendants' position in the litigation that: (1) prosecution history estoppel did not apply because isopropyl palmitate was no more than tangentially related to the rationale for the October 2001 amendment; and (2) Teva's generic version of AndroGel infringed under

the doctrine of equivalents. This is the very type of evidence that the district court suggested would support a denial of Teva's motion for summary judgment.

On December 20, 2011, the parties signed a binding term sheet, later memorialized in a definitive settlement and license agreement, to settle the litigation. Under the binding term sheet, Defendants licensed their AndroGel patents to Teva beginning no later than December 27, 2014—some 5.5 years before the expiration of the '894 patent—and Teva agreed not to market its generic AndroGel prior to the license date.[40] The agreement did not provide for any payment to Teva. The FTC, nevertheless, has challenged the settlement of the Teva patent litigation in Count II of the Complaint, which is the subject of a pending motion to dismiss. The current motion for summary judgment addresses the sham patent litigation element of the monopolization claim asserted by the FTC in Count I.

III. ARGUMENT

A. A Litigation Is Not a Sham Unless No Reasonable Litigant Could Expect to Prevail

Under the *Noerr-Pennington* doctrine, an "effort to influence the exercise of government power, even for the purpose of gaining an anticompetitive advantage, does not create liability under the antitrust laws." *FilmTec*, 67 F.3d at 937. In particular, the doctrine "generally immunizes a party from antitrust liability based on its filing of a lawsuit." *ERBE Elektromedizin*, 629 F.3d at 1291. The only relevant potential exception is the "narrow" one for "sham-litigation." *See id.*[41]

To prove sham litigation, the Commission or any other plaintiff must prove that the litigation at issue was: (1) "objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits," ***and*** (2) brought with a "subjective motivation" to "'interfere *directly* with the business relationships of a competitor'" rather than to prevail in the

[40] Dkt. 38, Hynd Decl. Ex. 1 (previously filed under seal on Nov. 12, 2014).

[41] The exception is "potential" because "[p]roof of sham merely deprives the [antitrust] defendant of immunity; it does not relieve the [antitrust] plaintiff of the obligation to establish all other elements of his claim." *PRE*, 508 U.S. at 61.

litigation. *PRE*, 508 U.S. at 60-61 (emphasis added). The Federal Circuit has held that these elements must be proved by clear and convincing evidence. *Golan v. Pingel Enter., Inc.*, 310 F.3d 1360, 1371 (Fed. Cir. 2002). But regardless of the standard of proof, the elements themselves are exacting, and for good reason: The Supreme Court "crafted the *Noerr-Pennington* doctrine—and carved out only a narrow exception for 'sham' litigation—to avoid chilling the exercise of the First Amendment right to petition the government for the redress of grievances." *Octane Fitness, LLC v. ICON Health & Fitness, Inc.*, 134 S. Ct. 1749, 1757 (2014). "The threat of antitrust liability," however, "chills the exercise of the right to petition." *Id.*

A lawsuit is objectively baseless only if the party that brought it had no "reasonabl[e] belie[f] that there [was] a *chance*" of prevailing. *PRE*, 508 U.S. at 62-63 (emphasis added). This is a high bar. As the courts have noted, this circumstance will be "rare," *id.* at 75 (Stevens, J., concurring in the judgment), and a court should reach the conclusion that it exists "only with great reluctance," *White v. Lee*, 227 F.3d 1214, 1232 (9th Cir. 2000). This is a reflection of the fact that the First Amendment guarantees parties broad latitude to assert claims and make arguments, even if those positions face an uphill battle. Thus, "objective baselessness is very difficult to prove, for a litigant's reasonable belief in its chance to achieve success on the merits is quite a low threshold." *Miller Pipeline Corp. v. British Gas PLC*, 69 F. Supp. 2d 1129, 1142 (S.D. Ind. 1999).

This rule is thus not meant to allow re-litigation of the underlying case to make some probabilistic determination, years later, about which side might have won. *See iLOR, LLC v. Google, Inc.*, 631 F.3d 1372, 1377 (Fed. Cir. 2011) ("Under this exacting standard, the plaintiff's case must have *no* objective foundation . . . ." (emphasis added)). Instead, in order to prove a sham with respect to legal issues, the FTC would have to identify binding precedent and show that Defendants had no reasonable argument available for distinguishing the precedent—factually or legally—or challenging it on appeal. Even unfavorable binding precedent does not in and of itself make a case a sham: parties may take legal positions that seem contrary to the weight of authority if the law is arguably unsettled, arguments exist to distinguish precedents, or

there are reasonable arguments to modify the law. *PRE*, 508 U.S. at 65. The Federal Circuit frequently reverses course on patent doctrines, and panels of that court frequently take conflicting or fact-bound positions.[42] The FTC thus cannot survive summary judgment with blithe assertions based on its preferred interpretation of the case law or predictions of how a district court or the Federal Circuit would have decided an issue several years ago.

With respect to factual issues, the FTC must identify an issue on which Teva or Perrigo would *indisputably* have won summary judgment in the patent case, because objective merit exists if there is a genuine dispute for the trier of fact to resolve. The Supreme Court has explained that "sham" is the opposite of "genuine," and that the Court intended to incorporate the summary judgment standard of Rule 56: a "genuine issue" is one that a court could not resolve against the plaintiff at summary judgment because the plaintiff has evidence on a material issue sufficient to permit the fact-finder to find in its favor. *PRE*, 508 U.S. at 61 (citing *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 250 (1986)). If a genuine factual dispute should have precluded summary judgment in the underlying case, then the underlying case was not a sham. *See Beckman Instruments, Inc. v. LKB Produkter AB*, 892 F.2d 1547, 1551 (Fed. Cir. 1989) (argument not "'baseless' when it survived a motion for summary judgment").

There are numerous cases in which courts have rejected claims of objective baselessness, despite the antitrust defendant's having *lost*—even before trial—the underlying litigation that it instituted as a plaintiff. *See, e.g.*, *Repeat-O-Type Stencil Mfg. Corp. v. Hewlett-Packard Co.*, 1998 WL 101699, at *2-3 (9th Cir. Mar. 9, 1998) (no objective baselessness for claims plaintiff lost on summary judgment because plaintiff argued for a reasonable extension of existing law); *Covad Commc'ns Co. v. Bell Atl. Corp.*, 398 F.3d 666, 677 (D.C. Cir. 2005) (no objective

[42] *See, e.g.*, Eileen M. Herlihy, *The Ripple Effect of Seventh Amendment Decisions on the Development of Substantive Patent Law*, 27 Santa Clara Computer & High Tech. L.J. 333, 400 (2011) (commenting that "the law of prosecution history estoppel has become enormously complex and confusing" and that "the complexity of the current law of prosecution history estoppel has in turn caused instability"); Donald S. Chisum, *Weeds and Seeds in the Supreme Court's Business Method Patents Decision: New Directions for Regulating Patent Scope*, 15 Lewis & Clark L. Rev. 11, 35 (2011) (noting the Federal Circuit's "tendency to fracture").

baselessness where patent court's analysis "went to some lengths to reject" the patentee's claims); *ERBE Elektromedizin*, 629 F.3d at 1291-92 (no objective baselessness in case in which the patentee lost summary judgment). Objective merit is a question of law when "there is no dispute over the predicate facts of the underlying legal proceeding." *PRE*, 508 U.S. at 63.[43] The "predicate facts" are the record of the underlying case and the facts and law available to the plaintiff at the time it brought that lawsuit. *Id.* Here, the state of the record, and the facts and law available to Defendants during the patent cases and at the time they were filed, are not in dispute.

B. The Perrigo Litigation Was Not a Sham

1. *The FTC's Own Statements Refute the Contention of Objective Baselessness*

The FTC cannot meet the exacting standard, let alone by clear and convincing evidence, to prove that the Perrigo litigation was a sham. The Court need look no further than the FTC's own statements to reach this conclusion. For over a decade, the FTC has consistently taken the position that a patent litigation settlement in which the parties "compromised on the time of entry without cash payments" is the best evidence of the strength of the patent. Petition for Writ of Certiorari at 9, *FTC v. Schering-Plough Corp.*, 548 U.S. 919 (2006) (No. 05-273), 2005 WL 2105243. Where, as here, the accused infringer gives up a significant portion of the remaining patent term without a cash payment, it follows directly that the patent claim was not frivolous. *See* Brief for Petitioner at 27-28, *FTC v. Actavis, Inc.*, 133 S. Ct. 2223 (2013) (No. 12-416), 2013 WL 267027, at *27-28. The Commission's public statements to this effect are numerous:

- "Under the Patent Act and this Court's precedents, a brand-name manufacturer's good-faith effort to enforce its patent through litigation cannot subject it to liability under the

[43] *See also, e.g.*, *Ethypharm S.A. Fr. v. Abbott Labs.*, 805 F. Supp. 2d 59, 70-71 (D. Del. 2011), *rev'd in part on another ground*, 707 F.3d 223 (3d Cir. 2013) ("[T]here is insufficient evidence of record from which a reasonable jury could conclude that Abbott's [infringement] theories were a sham, [so] the court grants Abbott's motion for summary judgment of no sham litigation . . . ."); *In re Terazosin Hydrochloride Antitrust Litig.*, 335 F. Supp. 2d 1336, 1359-60 (S.D. Fla. 2004) (granting summary judgment because "although [defendant's] interpretation of the [law] was a stretch, it did not exceed the pale of an aggressive attempt to extend the existing law, and thus was not objectively baseless" as a matter of law).

antitrust laws, even though the purpose of such litigation is to forestall competition. Nor should antitrust liability ordinarily attach to a settlement by which the parties to paragraph IV litigation simply agree on a compromise date of generic entry." *Id.* at 25.

- "[A] hypothetical settlement in which the parties compromised on a time of entry without cash payments *would reflect the strength of the patent as viewed by the parties*." Petition for Writ of Certiorari at 9, *Schering-Plough*, 548 U.S. 919 (2006) (No. 05-273), 2005 WL 2105243, at *9 (emphasis added).

- "[S]hort of a final court judgment on the issue, the parties' collective expectation of the outcome of their litigation—as reflected in a genuine, arms-length settlement—*represents the most accurate assessment of the subject patent's exclusionary power*. . . . Therefore, a hypothetical no-payment compromise on the entry-date would most accurately reflect their collectively expected outcome of litigation—i.e., the exclusionary power of Schering's patent." Brief of Respondent FTC at 44, *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005) (No. 04-10688), 2004 WL 3557972, at *44 (emphasis altered).

- "Many pharmaceutical patent cases have been settled by the parties' agreement on an entry date prior to the patent's expiration, but without payments by the patent holder. Such settlements can be defended on the ground that *any exclusion simply reflects the strength of the patent as understood by the parties*." Brief of the FTC as Amicus Curiae at 23, *In re K-Dur Antitrust Litig.*, 686 F.3d 197 (3d Cir. 2012) (Nos. 10-2077, 10-2078, 10-2079), 2011 WL 2115235, at *23 (emphasis added).

- "Such settlements—in which the parties to patent litigation settle by compromising the date of entry but without payments—are thus unlikely to entail any exclusion beyond that provided by the strength of the patent, and indeed may bring consumer benefits." Brief for Plaintiff-Appellant FTC at 51, *FTC v. Watson Pharms., Inc.*, 677 F.3d 1298 (11th Cir. 2012) (No. 10-12729), 2010 WL 5064779, at *51 (emphasis added).

- "[S]ince settlements without payments will tend to reflect patent strength, they can provide a benchmark for the consumer impact of either alternative." Jon Leibowitz, Chairman, FTC, *"Pay for Delay" Settlements in the Pharmaceutical Industry*, 2009 WL 1815435, at *7 (June 23, 2009).

[redacted] and the FTC has conceded that [redacted] therefore does not change the analysis: "The expected savings in the cost of litigation represent merely the transaction costs of litigation versus settlement and, therefore, do not affect the substantive merits of the dispute (i.e., the

expected outcome of the litigation)." Brief of Respondent FTC at 45 n.34, *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005) (No. 04-10688), 2004 WL 3557972.

The FTC suggests in its Complaint that, in this particular case, Perrigo had reasons to settle beyond the merits of the claim, such as the fact that the district court had scheduled the Teva trial within the next year. *See* Compl. ¶ 134. But parties to litigation routinely have multiple reasons to settle, and the FTC never qualified its proposed rule in this way. Indeed, it is well-known that most cases settle, and Defendants' settlement agreement with Perrigo was signed before Teva settled and contained no suggestion, much less a promise, that Defendants' case against Teva would be one of the minority that would go to trial. In any event, it defies common sense that a party would agree to stay off the market for any period of time, much less for three years, to settle a frivolous patent litigation which had no chance of succeeding. This is precisely the reason for the FTC's prior statements endorsing settlements without payments.

2. *Defendants Had an Objectively Reasonable Argument that Perrigo Infringed Under the Doctrine of Equivalents*

Even if the Court went beyond the FTC's prior judicial and other public statements, the uncontroverted evidence shows that Defendants had an objectively reasonable basis to assert that Perrigo's penetration enhancer was insubstantially different from Defendants', and thus the patent litigation fell squarely within the immunity provided under the *Noerr-Pennington* doctrine. It is true that claim 1 of the '894 patent, which is representative for purposes of this motion, specifies about 0.1% to about 5% isopropyl myristate as the penetration enhancer and Perrigo's generic testosterone gel uses isostearic acid, not isopropyl myristate. However, a product is infringing when it "meets every claim limitation either literally *or under the doctrine of equivalents*." *Pfizer, Inc. v. Teva Pharms. USA, Inc.*, 429 F.3d 1364, 1376 (Fed. Cir. 2005) (emphasis added). Courts have long recognized the doctrine of equivalents as an important safeguard against allowing an "unscrupulous copyist" to get around a patent by making "substitutions in the patent which, though adding nothing, would be enough to take the copied matter outside the claim" and thereby "place the inventor at the mercy of verbalism and . . .

deprive him of the benefit of his invention." *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 U.S. 605, 607-08 (1950).

The courts have held that a component of an accused composition is covered under the doctrine of equivalents when it performs substantially the same function in substantially the same way to achieve substantially the same result as an element in the patent claim. *Warner-Jenkinson*, 520 U.S. at 40; *Atlas Powder Co. v. E.I. du Pont De Nemours & Co.*, 750 F.2d 1569, 1580 (Fed. Cir. 1984) (asking whether "the changed ingredient has the same purpose, quality, and function as the claimed ingredient").

Under this rubric, Defendants had an objectively reasonable argument that isostearic acid and isopropyl myristate are equivalents. Karande Decl. ¶¶ 3-4. As explicated in Dr. Karande's Declaration, this is because isopropyl myristate and isostearic acid exhibit several similarities in their structural and molecular properties—like their similar carbon tails. *Id.* ¶¶ 4, 24-29. These are directly relevant in establishing their substantially identical mode of action as penetration enhancers. *Id.* ¶¶ 24-29. Further bolstering the conclusion that Defendants had an objectively reasonable argument that Perrigo's penetration enhancer isostearic acid was and is an equivalent of isopropyl myristate is the fact that, in its paragraph IV notice, Perrigo did not meaningfully contest that its penetration enhancer met this test. Likewise, the FDA has now granted Perrigo's product an AB bioequivalence rating to AndroGel notwithstanding the different penetration enhancer.[44]

3. *Arguments from Other Proceedings, Regarding Application of Different Legal and Regulatory Standards, Do Not Show Objective Baselessness*

Unable to show that Defendants' infringement contentions lacked a reasonable factual foundation or were indisputably foreclosed by binding precedent, the FTC fills its Complaint with sentence fragments from arguments made by Defendants in other proceedings in which infringement under the doctrine of equivalents was not even at issue or relevant. Compl. ¶¶ 72-

[44] Ex. 28, FDA Decision re: Docket Nos. FDA-2011-P-0610 and FDA-2013-P-0371, at 29-31 (July 23, 2014).

77. The FTC seemingly contends that these decontextualized phrases are in tension with Defendants' allegations in the Perrigo patent infringement litigation that the Perrigo penetration enhancer was an equivalent to isopropyl myristate, or constitute admissions that the claims against Perrigo were frivolous.[45]

The FTC's contentions are misplaced. The statements to which the FTC points, and others like them, are not inconsistent with Defendants' assertion of infringement under the doctrine of equivalents, much less clear and convincing evidence of a sham. Those statements arose in different proceedings involving different issues governed by different legal and regulatory standards. In any event, both of the agencies that considered these arguments rejected them and concluded that the distinctions being made between the two penetration enhancers were not relevant.[46]

(a) ***Statements regarding bioequivalence from Defendants' citizen petition are not evidence of objective baselessness***

Defendants argued to the FDA that the data submitted by Perrigo (and Teva) failed to demonstrate that their products were therapeutically equivalent to AndroGel.[47] *See* Compl. ¶ 77. Even setting aside the fact that the FDA later found that Perrigo's product is bioequivalent and therapeutically equivalent to AndroGel—which alone disposes of any contention that extrajudicial statements challenging bioequivalence or therapeutic equivalence show objective baselessness—the contention would be unjustified as a matter of law because "bioequivalency and equivalent infringement are different inquiries." *Abbott Labs v. Sandoz, Inc.*, 566 F.3d 1282,

[45] The Complaint does not recount similar statements with respect to Teva's penetration enhancer isopropyl palmitate. Insofar as the statements do apply to Teva's penetration enhancer, Defendants' responsive arguments proffered here with respect to Perrigo apply equally to Teva.

[46] The Complaint also references a 2009 internal document from Solvay Pharmaceuticals, which stated Solvay's determination at that time that there was not a sufficient basis to bring patent litigation against Perrigo. Compl. ¶ 4. Solvay was Unimed's parent company and was acquired by Abbott Laboratories only in 2010. *See Ethypharm S.A. Fr. v. Abbott Labs.*, 271 F.R.D. 82, 84 (D. Del. 2010). Defendants were not and are not bound by Solvay's purported determination when it was a separate corporate entity.

[47] Ex. 26, Citizen Petition Supplement of AbbVie Inc., FDA-2011-P-0610-0004 (Dec. 21, 2012); Ex. 27, Citizen Petition Supplement of AbbVie Inc., FDA-2011-P-0610-0005 (Dec. 11, 2013).

1298 (Fed. Cir. 2009). "Bioequivalency is a regulatory and medical concern aimed at establishing that two compounds are effectively the same for pharmaceutical purposes. In contrast, equivalency for purposes of patent infringement requires an element-by-element comparison of the patent claim and the accused product . . . ." *Id*. In other words, the bioequivalence inquiry asks if one *compound* (as a whole) is effectively the same as another; the doctrine of equivalents inquiry asks if one *component* (individually) is insubstantially different from one single claim element.

At no time during Perrigo's or Teva's FDA approval process did Defendants argue that either product could not be approved because it used a different penetration enhancer than AndroGel used, or because it used a penetration enhancer that performed a substantially different function than AndroGel's penetration enhancer. Rather, the primary issue was whether Perrigo's or Teva's product had as low a transferability risk as AndroGel did, because risk of transfer of topical testosterone to women and children must be considered.[48]

Nothing in the '894 patent limits the claims to products that are bioequivalent to AndroGel or to any other product falling within the literal scope of the claims.[49] Indeed, a testosterone product using the very same penetration enhancer that AndroGel uses (isopropyl myristate) could literally infringe the '894 patent yet fail to meet the FDA standard for bioequivalency to AndroGel. The patent also makes no claims regarding skin transfer, much less requiring that every infringing product have the same (or an insubstantially different) skin transfer risk profile as AndroGel or any other product falling within the claims' literal scope.[50]

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[48] Ex. 26, Citizen Petition Supplement of AbbVie Inc., FDA-2011-P-0610-0004 (Dec. 21, 2012); Ex. 27, Citizen Petition Supplement of AbbVie Inc., FDA-2011-P-0610-0005 (Dec. 11, 2013); *see also* Ex. 12, FDA/CDER Response to Auxilium Pharmaceuticals, Inc., FDA-2009-P-0123-0011, at 4-5 (Aug. 26, 2009) ("variations in the penetration enhancers might affect the amount of residual product left on the skin of the patient as well as the amount and rate of absorption of the product in a person who comes into contact with the patient being treated with the product").

[49] Ex. 8, '894 patent at 49:59-52:60.

[50] *Id.*

Accordingly, it is meritless for the FTC to rely on Defendants' arguments to the FDA as purported evidence of objective baselessness.

(b) ***Statements regarding obviousness and known interchangeability from other patent prosecutions and other litigation are not evidence of objective baselessness***

Both before and after issuance of the '894 patent, Unimed applied for additional patents relating to testosterone gels. The Complaint identifies four excerpts from arguments made during these prosecutions as purported evidence of objective baselessness. Compl. ¶¶ 7, 76.[51] The Complaint also identifies a statement from an expert report submitted by Defendants in earlier litigation involving the '894 patent against two other generic manufacturers, Watson Pharmaceuticals and Paddock Laboratories. *Id.* ¶ 74.[52] These statements are also legally and factually inapposite to the applicability of the doctrine of equivalents and therefore not evidence that Defendants' infringement contentions are objectively baseless.

The patent prosecution statements were made in response to rejections by the patent examiner for obviousness, and the statement from the Watson/Paddock litigation similarly arose in an expert report addressing nonobviousness. That should be the end of this theory of objective baselessness because "equivalence" is not "tantamount to obviousness"; "[t]he two legal principles require different analytical frameworks." *Siemens Med. Solutions USA, Inc. v. Saint-Gobain Ceramics & Plastics, Inc.*, 637 F.3d 1269, 1282 (Fed. Cir. 2011). The obviousness inquiry asks whether "a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention" as a whole. *Procter & Gamble Co. v. Teva Pharms. USA, Inc.*, 566 F.3d 989, 994 (Fed. Cir. 2009). In contrast, the doctrine of equivalents inquiry asks whether the putative equivalent is in fact insubstantially different from a particular claim limitation. *Abbott Labs.*, 566 F.3d at 1298 (doctrine of equivalents "requires an element-by-element comparison").

[51] These patent prosecution statements appear in Ex. 31, Ex. 33 at 15-16, and Ex. 35 at 9.
[52] This statement from an earlier expert report appears in Ex. 37 at 8. The prior art reference discussed in the cited passage of the expert report is attached as Ex. 38.

All of the cited statements concerned the evidence (or lack thereof) of *known substitutability* of penetration enhancers in a composition such as AndroGel. Known substitutability is highly relevant to obviousness, and in some instances dispositive. *See KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 416 (2007) ("when a patent claims a structure already known in the prior art that is altered by the mere substitution of one element for another known in the field, the combination must do more than yield a predictable result" in order to be nonobvious). For the doctrine of equivalents, known substitutability or interchangeability is one factor that "weighs in favor of finding infringement." *Ring & Pinion Serv., Inc. v. ARB Corp.*, 743 F.3d 831, 834 (Fed. Cir. 2014). On the other hand, a lack of known interchangeability does *not* militate against a finding of equivalence. *See, e.g.*, *Abraxis Bioscience, Inc. v. Mayne Pharma (USA) Inc.*, 467 F.3d 1370, 1382 (Fed. Cir. 2006) (rejecting the argument that "the lack of known interchangeability between [two] antimicrobial agent[s] mandate[d] the conclusion that the accused product d[id] not infringe under the doctrine of equivalents"). Even an "after-arising technology, a technology that did not exist at the time of patenting, can be found to be an equivalent under the doctrine of equivalents." *Ring & Pinion*, 743 F.3d at 835. Put another way, it can be true both: (1) that an ingredient used by an alleged infringer is in fact insubstantially different from the one literally claimed in the patent (and therefore an infringing equivalent), and (2) that at the time of the claimed invention, a person of ordinary skill would not know from the prior art that the two ingredients were obviously interchangeable.

Moreover, the FTC's allegations fail to recognize that the examiner *never accepted any of these arguments* in these prosecutions. The examiner concluded instead that isostearic acid *was* shown by the prior art to be interchangeable.[53] Whatever inconsistency the FTC believes is shown by Unimed's prosecution arguments is undermined by the examiner's conclusions that these penetration enhancers were known to be interchangeable. *See Ring & Pinion*, 743 F.3d at

[53] Ex. 32 (Unimed's abandonment of the application referred to in Ex. 31, with no claims allowed); Ex. 36 at 13 -14 (examiner's rejection of Unimed's argument made in Ex. 35).

834 ("known interchangeability weighs in favor of finding infringement under the doctrine of equivalents.").[54] Accordingly, it could not be objectively baseless for Defendants to take a position that the penetration enhancers were equivalent in the patent litigation given that the examiner had concluded the same thing.

4. *Defendants Had an Objectively Reasonable Argument that Prosecution History Estoppel Did Not Apply*

The central substantive issue on Defendants' patent infringement claim against Perrigo was whether PHE barred Defendants' assertion of infringement under the doctrine of equivalents. The Second Amendment was the one that was relevant to this issue, because that is where Defendants deleted the claims' literal coverage of Perrigo's penetration enhancer, isostearic acid, which had been expressly listed in the previously pending claims. As discussed above, PHE may bar application of the doctrine of equivalents *only* when the relevant amendment to the patent application narrowed the claim's scope for a reason related to patentability. *Festo*, 535 U.S. at 735. This is an objective determination made based upon the information in the patent's file history. *Festo*, 344 F.3d at 1369-70.

Defendants' contention that the Second Amendment was not made for reasons of patentability was certainly reasonable, and far from frivolous. The examiner never rejected claim 1 as it had been amended in the First Amendment. Indeed, she could not have done so without re-examining the claim as amended and providing a reasoned analysis. 35 U.S.C. § 132(a). The examiner did not do this. Although the examiner noted that claim 47 (requiring either isopropyl myristate or lauryl alcohol) would be allowable, she never stated that a claim would *not* be allowable if it included any of the other penetration enhancers listed in the

[54] Similarly, the reference discussed in Unimed's expert report cited in the Complaint describes a penetration enhancer system that includes one of 91 possible fatty acid esters and one of 17 different alcohols, for a total of 91 × 17 = 1,547 potential penetration enhancer systems. It does not discuss whether any particular pair of penetration enhancer systems out of the 1,547 can be substitutable for one another in a transdermal gel containing testosterone. *See* Ex. 38 at 2-3.

previously pending claim, nor did she cite any prior art that disclosed those other penetration enhancers in a testosterone composition.

In the absence of a rejection, Defendants could not have appealed from the examiner's failure to allow the claim as it existed before the Second Amendment. The Supreme Court in *Festo* emphasized the importance of this procedural context to the application prosecution history estoppel:

> When . . . the patentee originally claimed the subject matter alleged to infringe, but then narrowed the claim *in response to a rejection*, he may not argue that the surrendered territory comprised unforeseen subject matter that should be deemed equivalent to the literal claims of the issued patent. . . . A rejection indicates that the patent examiner does not believe the original claim could be patented. While the patentee has the right to appeal, his decision to forego an appeal and submit an amended claim is taken as a concession that the invention as patented does not reach as far as the original claim.

Festo, 535 U.S. at 733-34 (emphasis added). Here, in contrast, there was no such rejection, no right to appeal, and no concession that a composition comprising the penetration enhancers in the first amended claim (as it existed before the Second Amendment) could not be patented. In fact, Defendants continued to seek claims reciting additional penetration enhancers, including isostearic acid, in several patent applications filed since the Second Amendment which claim priority to the '894 patent.[55]

Moreover, the objective evidence here presents a clear alternative reason for Defendants having made the Second Amendment. *See Loral Fairchild Corp. v. Sony Corp.*, 181 F.3d 1313, 1325, 1327 (Fed. Cir. 1999) (the court "must examine the reasoning behind the amendment to determine if it was made for purposes of patentability" and, in so doing, "the entire record must be analyzed using an objective standard"). Time was of the essence in the prosecution of the '777 application through issuance of the patent. As noted, the '777 application was filed in August 2000, and regulatory exclusivity for AndroGel under 21 U.S.C. § 355(j)(5)(F)(iii) (new clinical study exclusivity) was set to expire at the end of February 2003. In 2001, the *average*

[55] *See supra* note 20 and accompanying text.

time of pendency for an issued patent in the Biotechnology & Organic Chemistry sector was 27.5 months.[56] If this were an "average" patent prosecution, then, the patent would likely issue only slightly before regulatory exclusivity for AndroGel expired. If the process took longer than the average, Defendants would have had no intellectual property rights to assert against the marketing of a generic version of AndroGel—even though that generic might be a direct copy of AndroGel and infringed Unimed's subsequently granted patents.

A decision to speed the issuance of a patent containing claims that an examiner indicated she would allow while continuing to seek different claims through other patent applications is a common prosecution strategy, as recognized by a then-Federal Trade Commissioner. *See* William E. Kovacic, *Intellectual Property Policy and Competition Policy*, 66 N.Y.U. Ann. Surv. Am. L. 421, 432 (2011) ("[p]atent applicants frequently use [this strategy] . . . to pursue additional patents having claims of different scope than those previously allowed.").

C. The Teva Litigation Was Not a Sham

1. *Prosecution History Estoppel Does Not Apply If the Rationale for the Amendment Is Tangential to the Alleged Equivalent*

The suit against Teva for infringement of the '894 patent by Teva's generic AndroGel also falls squarely within the immunity provided under the *Noerr-Pennington* doctrine. Defendants had a reasonable argument that PHE did not bar their equivalents contention.

As with respect to the Perrigo penetration enhancer, the FTC's Complaint does not allege that Defendants lacked a reasonable argument for contending that Teva's penetration enhancer—isopropyl palmitate—satisfied the test for infringement under the doctrine of equivalents.[57] The Complaint alleges that Teva's penetration enhancer was originally within the literal scope of

[56] Ex. 29, U.S. Patent & Trademark Office, *Performance and Accountability Report Fiscal Year 2001*, at 109, *available at* www.uspto.gov/about/stratplan/ar/USPTOFY2001PAR.pdf.

[57] Even if the Complaint did obliquely state such an allegation, the direct evidence demonstrates that Defendants' assertion of the equivalence of isopropyl myristate and isopropyl palmitate was and is not objectively baseless. In his declaration, Dr. Hadgraft states his expert opinion that, when used in a transdermal testosterone gel, isopropyl palmitate and isopropyl myristate are equivalents. Hadgraft Decl. ¶¶ 7, 25-33. This would certainly suffice to show that Defendants had a reasonable equivalence argument against Teva.

claim 1 of the patent application but, after the First Amendment, was not literally claimed. But this only raises the question of whether PHE applies; it does not dictate the outcome of the PHE analysis, which remained an open issue and the reasonable subject of the patent litigation, as evidenced by the court's reserving judgment on Teva's motion for summary judgment until appropriate discovery could be taken.

In *Festo*, the Supreme Court rejected the rigid approach on which the Complaint depends, and held that even where an amendment is made for purposes of patentability, it does not mean that PHE must apply. Instead, there are important exceptions, including the situation in which "the rationale underlying the amendment may bear no more than a tangential relation to the equivalent in question." *Festo*, 535 U.S. at 740-41; *see also Festo*, 344 F.3d at 1368 (on remand). As the Supreme Court explained:

> Nor is there any call to foreclose claims of equivalence for aspects of the invention that have only a peripheral relation to the reason the amendment was submitted. . . . [T]here is no more reason for holding the patentee to the literal terms of an amended claim than there is for abolishing the doctrine of equivalents altogether and holding every patentee to the literal terms of the patent.

Festo, 535 U.S. at 738.

The Federal Circuit has applied this "tangential" or "peripheral" exception subsequent to *Festo*. For example, in *Insituform Technologies, Inc. v. CAT Contracting, Inc.*, 385 F.3d 1360 (Fed. Cir. 2004), the original patent application would have literally covered what would later become the accused product. Like the patent applicants here, the *Insituform* applicant amended its application to traverse a rejection, and following the amendment, the claims no longer literally read on the accused product. The patent later issued. The Federal Circuit held that, despite a narrowing amendment in response to a rejection, PHE did not bar a finding of infringement under the doctrine of equivalents. The Federal Circuit noted that "Insituform never stated that the problem could not be solved by using" a method different from the single method specified in the amended claim, and that there was "no indication in the prosecution history of any relationship between the narrowing amendment and . . . the alleged equivalent." *Id*. at 1369-70. Accordingly, the Federal Circuit held that the "plaintiffs ha[d] successfully rebutted the *Festo*

presumption by establishing that the amendment narrowing the claimed invention []was tangential" to the alleged equivalent. *Id.* at 1370; *accord Primos, Inc. v. Hunter's Specialities, Inc.*, 451 F.3d 841, 848-49 (Fed. Cir. 2006); *McKesson Automation, Inc. v. Swisslog Italia S.P.A.*, 712 F. Supp. 2d 283, 302-03 (D. Del. 2010); *Engineered Prods. Co. v. Donaldson Co.*, 313 F. Supp. 2d 951, 973-74 (N.D. Iowa 2004).

2. *There Was an Objectively Reasonable Argument that the Rationale for the Amendment Was Tangential to Isopropyl Palmitate*

Defendants had an objectively reasonable argument that the First Amendment's dropping of isopropyl palmitate from claim 1's literal scope was only tangential to the purpose of that amendment. In the rejection of the original claims, the examiner identified only two disclosures of penetration enhancers in the prior art, both of which were penetration enhancers listed in the specification of the application: oleic acid, which was disclosed in the *Mak* reference, and isopropyl myristate, which was disclosed in the *Allen* reference. Unimed acquiesced in the examiner's rejection in view of *Mak* by narrowing its claims to exclude oleic acid. But Unimed did not acquiesce in the examiner's view that isopropyl myristate and other substances like it were obvious as penetration enhancers; indeed, Unimed continued to pursue and eventually obtained claims reciting isopropyl myristate.

Isopropyl palmitate is arguably almost identical to isopropyl myristate. Hadgraft Decl. ¶¶ 26-29. Teva itself stated in its NDA that isopropyl palmitate "was selected as a penetration enhancer as it is chemically similar to isopropyl myristate."[58] The similarity in the names of isopropyl myristate and isopropyl palmitate is no accident: "Myristate" is the nomenclature for a fatty acid with 14 carbon atoms; "palmitate" is the nomenclature for a fatty acid with 16 carbon atoms.[59] In all other respects, the two penetration enhancers are chemically the same. Hadgraft Decl. ¶¶ 26-29. As Professor Hadgraft explains in his declaration, oleic acid functions as a penetration enhancer differently from how isopropyl myristate functions. Professor Hadgraft

[58] Ex. 20 at 21.
[59] Ex. 30, A.D. Johnson, 2 *The Testis: Biochemistry* 195 tbl. I (1970).

also explains that isopropyl palmitate—Teva's penetration enhancer—is distinguishable from oleic acid in precisely the same ways. *Id.* ¶¶ 47-48, 55-56.

The opinions set forth in Professor Hadgraft's declaration establish that Defendants' position could not be a sham. They establish a reasonable scientific basis for Defendants' argument that PHE did not apply because the relevant amendment was tangential to the alleged equivalent. *See Intervet Inc. v. Merial Ltd.*, 617 F.3d 1282, 1292 (Fed. Cir. 2010) (finding PHE inapplicable in a case involving gene sequences, as rationale of amendment limiting claims to certain porcine gene sequences was tangential to a porcine gene sequence excluded by the language of the amendment); *Cordis Corp. v. Medtronic Ave, Inc.*, 336 F. Supp. 2d 363, 369-70 (D. Del. 2004) (finding tangentiality exception to PHE applicable in a case involving coronary stents, because the accused stent was more similar to the inventive stent than the prior art stent that prompted the narrowing amendment). It was hardly surprising for the district judge to state that the court would probably deny summary judgment if the expert reports were in conflict,[60] because the expert opinions would be directly relevant to the tangentiality issue. *See Festo*, 344 F.3d at 1370 ("whether the patentee has established a merely tangential reason for a narrowing amendment is for the court to determine" based on evidence including, "when necessary, testimony from those skilled in the art as to the interpretation of [the prosecution] record"). The denial of a Rule 56 summary judgment motion because of a genuine dispute of fact means the litigation cannot be a sham because, as the Supreme Court has stated, *PRE*'s objective inquiry mirrors the "genuine issue" standard under Rule 56. *PRE*, 508 U.S. at 61 (1993) ("To be sham, therefore, litigation must fail to be 'genuine' . . . ."); *see also VAE Nortrak N. Am., Inc. v. Progress Rail Servs. Corp.*, 459 F. Supp. 2d 1142, 1166 (N.D. Ala. 2006) (no sham litigation where there were genuine issues of material fact on infringement); *Honeywell*, 343 F. Supp. 2d at

[60] Ex. 24, Dkt. 65, Hr'g Tr., Oct. 14, 2011, at 75, *Abbott Prods., Inc. v. Teva Pharms. USA, Inc.*, No. 1:11-cv-384 (D. Del.) ("[T]he *Festo* case seems to allow expert -- some expert testimony. If there are experts, it's likely that they're not going to agree. If they don't agree, summary judgment probably would be denied.").

325-26 (no sham litigation because patentee had highly qualified expert backing infringement theory); *Shire*, 2008 WL 4402251, at *13 (no sham litigation where court found the "existence of issues of material fact regarding the infringement").

IV. CONCLUSION

Defendants' patent claims in the Perrigo and Teva litigation were not, as a matter of law, objectively baseless, and therefore do not fall within the narrow "sham" exception to the *Noerr-Pennington* doctrine of antitrust immunity. Accordingly, Defendants respectfully request that the Court enter summary judgment in their favor on Count I of the FTC's Complaint.

February 6, 2015

Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned certifies that on the 6th day of February 2015 the foregoing AbbVie and Besins Defendants' Motion for Summary Judgment on Count I of the Complaint (Public Version – Confidential Information Redacted) was filed with the United States District Court for the Eastern District of Pennsylvania using the ECF system. This document is available for reviewing and download. The undersigned certifies that he also served the foregoing Motion for Summary Judgment on Count I of the Complaint on all counsel of record via electronic mail.

/s/ *Todd N. Hutchison*
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